CLAIMS amended based on Article 34

1. (Amended) A medicament-containing particle wherein an unpleasant taste of the medicament is alleviated, which is obtainable by mixing and granulating the following ingredients:

(1) the medicament with an unpleasant taste,

(2) methylcellulose, and

(3) mannitol,

wherein the amount of the methylcellulose is about 0.8 to about 10 parts by weight per 1 part by weight of the medicament with an unpleasant taste.

2. (Deleted)

3. (Deleted)

4. The medicament-containing particle according to claim 1 wherein the amount of the methylcellulose is about 0.8 to about 5 parts by weight per 1 part by weight of the medicament with an unpleasant taste.

5. (Amended) The medicament-containing particle according to claim 1 or 4 wherein the amount of the mannitol is about 0.3 to about 50 parts by weight per 1 part by weight of the

methylcellulose.

6. (Amended) The medicament-containing particle according to claim 1 or 4 wherein the amount of the mannitol is about 0.5 to about 12 parts by weight per 1 part by weight of the methylcellulose.

7. (Amended) The medicament-containing particle according to claim 1 or 4 wherein the amount of the mannitol is about 0.7 to about 7.5 parts by weight per 1 part by weight of the methylcellulose.

8. (Amended) The medicament-containing particle according to any one of claim 1 and claims 4 - 7 wherein the mannitol is D-mannitol.

9. (Amended) The medicament-containing particle according to any one of claim 1 and claims 4 - 8 wherein the medicament with an unpleasant taste is 4-amino-5-chloro-2-ethoxy-N-[[4-(4-fluorobenzyl)-2-morpholinyl]methyl]-benzamide or a pharmaceutically acceptable salt thereof.

10. (Amended) The medicament-containing particle according to claim 1 which is obtainable by mixing and granulating the following ingredients:

AMENDED SHEETS

(1) (±)-4-amino-5-chloro-2-ethoxy-N-[[4-(4-fluorobenzyl)-2-morpholinyl]methyl]benzamide citrate dihydrate as a medicament,

(2) methylcellulose, and

(3) D-mannitol,

wherein the amount of the methylcellulose is about 0.8 to about 10 parts by weight per 1 part by weight of (±)-4-amino-5-chloro-2-ethoxy-N-[[4-(4-fluorobenzyl)-2-morpholinyl]methyl]benzamide citrate, and

the amount of the D-mannitol is about 0.3 to about 50 parts by weight per 1 part by weight of the methylcellulose.

11. (Amended) A solid preparation comprising the medicament-containing particle set forth in any one of claim 1 and claims 4 - 10 and other pharmaceutically acceptable ingredients for pharmaceutical preparation.

12. The solid preparation according to claim 11 which is a tablet-like preparation or a granule-like preparation.

13. The solid preparation according to claim 12 wherein the tablet-like preparation is in the form of a tablet or a pill.

14. The solid preparation according to claim 12 wherein

the granule-like preparation is in the form of a granule, a fine granule or a powder.

15. The solid preparation according to any one of claims 11 - 14 which is an intrabuccally rapidly disintegrating preparation.

16. The solid preparation according to claims 15 wherein the intrabuccally rapidly disintegrating preparation is in the form of a tablet.

17. The solid preparation according to claim 15 wherein the intrabuccally rapidly disintegrating preparation is a granule-like preparation.

18. The intrabuccally rapidly disintegrating preparation set forth in any one of claims 15 - 17 which is characterized by the following properties:

(i) disintegrating within 40 seconds on a tongue of a healthy adult with his mouth closed and without chewing,

(ii) dissolving at a substantial dissolution rate of 85% or more after 15 minutes according to the dissolution test described in the Japanese Pharmacopoeia XIV [using Method 2 (50 rpm) for tablets or Method 1 (50 rpm) for granule-like preparation, resolution medium : 900 mL of

water], and

(iii) not substantially feeling an unpleasant taste on setting the preparation in buccal cavity.

19. A composition for preparing the intrabuccally rapidly disintegrating preparation set forth in claim 15, which comprises

a medicament-containing particle wherein an unpleasant taste of the medicament is alleviated, which is obtainable by mixing and granulating the medicament with an unpleasant taste, methylcellulose and mannitol;

an excipient; and

a disintegrator.

20. (Amended) A process for preparing a medicament-containing particle wherein an unpleasant taste of the medicament is alleviated, which is obtainable by mixing (1) the medicament with an unpleasant taste, (2) methylcellulose whose amount is about 0.8 to about 10 parts by weight per 1 part by weight of the medicament with an unpleasant taste and (3) mannitol, and granulating the mixture with water or a water-containing solvent.

21. A commercial package which comprises the solid

preparation set forth in claim 11 comprising 4-amino-5-chloro-2-ethoxy-N-[[4-(4-fluorobenzyl)-2-morpholinyl]-methyl]benzamide or a pharmaceutically acceptable salt thereof as a medicament with an unpleasant taste; and a written matter as to the solid preparation,

including a description on the outside of the package or in the written matter inside the package which intends that the solid preparation can/should be used for promoting gastrointestinal motility, improving postgastrectomy condition, or preventing/treating gastroesophageal reflux disease (GERD).

請　求　の　範　囲

1．（補正後）下記の成分：

（1）不快な味を有する薬物、

（2）メチルセルロースおよび

（3）マンニトール

を混合し粒子化してなる薬物の不快な味を低減した薬物含有粒子であって、不快な味を有する薬物１重量部に対して、メチルセルロースを約０．８～約１０重量部程度の割合で含む薬物含有粒子。

2．（削除）

3．（削除）

4．不快な味を有する薬物１重量部に対して、メチルセルロースを約０．８～約５重量部程度の割合で含む請求項１記載の薬物含有粒子。

5．（補正後）メチルセルロース１重量部に対して、マンニトールを約０．３～約５０重量部程度の割合で含む請求項１または４に記載の薬物含有粒子。

6．（補正後）メチルセルロース１重量部に対して、マンニトールを約０．５～約１２重量部程度の割合で含む請求項１または４に記載の薬物含有粒子。

7．（補正後）メチルセルロース１重量部に対して、マンニトールを約０．７～約７．５重量部程度の割合で含む請求項１または４に記載の薬物含有粒子。

8．（補正後）マンニトールがＤ－マンニトールである請求項１又は４～７のいずれかに記載の薬物含有粒子。

9．（補正後）不快な味を有する薬物が、４－アミノ－５－クロロ－２－エトキシ－Ｎ－［［４－（４－フルオロベンジル）－２－モルホリニル］メチル］ベンズアミドまたはその生理学的に許容される塩である請求項１又は４～８のいずれかに記載の薬物含有粒子。

１０．（補正後）（１）（±）－４－アミノ－５－クロロ－２－エトキシ－Ｎ－［［４－（４－フルオロベンジル）－２－モルホリニル］メチル］ベンズアミドのクエン酸塩２水和物、

（2）メチルセルロースおよび

（３）Ｄ－マンニトール

を混合し粒子化してなる請求項１に記載の薬物含有粒子であって、

（±）－４－アミノ－５－クロロ－２－エトキシ－Ｎ－［［４－（４－フルオロベンジル）－２－モルホリニル］メチル］ベンズアミドのクエン酸塩　１重量部に対してメチルセルロースを約０．８～約１０重量部程度、メチルセルロース１重量部に対してＤ－マンニトールを約０．３～約５０重量部程度の割合で含む薬物含有粒子。

１１．（補正後）請求項１又は４～１０のいずれかに記載の薬物含有粒子と薬学的に許容される製剤化成分を含む固形製剤。

１２．固形製剤が錠剤状製剤または粒状製剤である請求項１１に記載の固形製剤。

１３．錠剤状製剤が錠剤または丸剤である請求項１２に記載の固形製剤。

１４．粒状製剤が、顆粒剤、細粒剤または散剤である請求項１２に記載の固形製剤。

１５．固形製剤が口腔内速崩壊製剤である請求項１１～１４のいずれかに記載の固形製剤。

１６．口腔内速崩壊製剤が錠剤である請求項１５に記載の固形製剤。

１７．口腔内速崩壊製剤が粒状製剤である請求項１５に記載の固形製剤。

１８．次の特性を備えることを特徴とする請求項１５～１７のいずれかに記載の口腔内速崩壊製剤：

（i）本製剤を健常成人の舌のうえに置き、閉口のまま噛まない状態において４０秒以内に崩壊し、

(ii)日本薬局方第１４改正に記載の溶出試験（錠剤においては第２法（５０回転／分）、粒状製剤においては第１法（５０回転／分）、溶媒：水９００ｍｌ）において、１５分後の溶出率が実質的に８５％以上であり、

（iii）本製剤を口に含むとき、実質的に不快な味を感じない。

１９．（補正後）請求項１５に記載の口腔内速崩壊製剤を製造するための組成物であって、不快な味を有する薬物、メチルセルロース及びマンニトールを混合し粒子化してなる不快な味を低減した薬物含有粒子、賦形剤、並びに崩壊剤を含有する組成物。

２０．（補正後）（１）不快な味を有する薬物、（２）不快な味を有する薬物１重量部に対して、約０．８～約１０重量部程度の量のメチルセルロースおよび（３）マンニトールを混合し、水または含水溶媒を用いて粒子化することを特徴とする薬物の不快な味を低減した薬物含有粒子の製造方法。

２１．不快な味を有する薬物として４－アミノ－５－クロロ－２－エトキシ－Ｎ－［［４－（４－フルオロベンジル）－２－モルホリニル］メチル］ベンズアミドまたはその生理学的に許容される塩を含む請求項１１に記載の固形製剤及び当該固形製剤に関する記載物を含む商業パッケージであって、当該固形製剤を消化管運動機能促進、胃切除後症状の改善又は胃食道逆流症（GERD）の予防若しくは治療に使用することができる又は使用すべきである旨の記載を、該パッケージ上又は該パッケージ内の記載物に含む商業パッケージ。